UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ROCHE DIAGNOSTICS CORPORATION, ROCHE DIAGNOSTICS OPERATIONS, INC., and CORANGE INTERNATIONAL, LTD., Plaintiffs/Counterclaim Defendants,	)	
vs.	)	1:04-cv-0358-LJM-VSS
APEX BIOTECHNOLOGY CORP., HYPOGUARD USA, INC., and MEDLINE INDUSTRIES, INC., Defendants/Counterclaim Plaintiffs.	)	
ROCHE DIAGNOSTICS CORPORATION, ROCHE DIAGNOSTICS OPERATIONS, INC., and CORANGE INTERNATIONAL, LTD., Plaintiffs/Counterclaim Defendants,	)	
vs.	)	1:04-cv-1187-LJM-VSS
HOME DIAGNOSTICS CORPORATION, INC., Defendant/Counterclaim Plaintiff.	)	

MEMORANDUM AND OPINION ON
DEFENDANTS' INEQUITABLE CONDUCT COUNTERCLAIM

On May 31, June 1-2, 2005, this Court heard evidence and argument on defendants'/counterclaimants', Apex Biotechnology Corp ("Apex"), Hypoguard USA, Inc., Medline Industries, Inc. ("Medline") and Home Diagnostics Corporation, Inc. ("HDI") (collectively, "Defendants"), inequitable conduct counterclaim against plaintiffs/counterdefendants Roche Diagnostics Corporation, Roche Diagnostics Operations, Inc. and Corange International, Ltd.

(collectively, "Roche"). The following memorandum opinion and order is intended to serve as the Court's findings of facts and conclusions of law.

I. FACTUAL BACKGROUND

A. THE TALL OAK[1] PATENT FAMILY

This suit is based on a family of patents originally filed by a small company called Tall Oak. *See* Exh. 15, Excerpt of File History of U.S. Application No. 168,295, at A1 ("'295 App. History"). The most significant patents in the family for purposes of this suit is U.S. Patent No. Re 36,268 (the "'268 patent"), which is a re-issue of U.S. Patent No. 5,108,564 (the "'564 patent"). The original application for the invention of the patent family was filed on March 15, 1988, and named as inventors Dr. Paul A. Pottgen ("Dr. Pottgen") and Mr. Neil Szuminsky ("Szuminsky"). *Id.* In October 1988, Tall Oak filed a petition to add Dr. Jonathan L. Talbott ("Dr. Talbott") as an inventor, and in March 1989, the company filed a continuation-in-part ("CIP") application that added Dr. Joseph Jordan ("Dr. Jordan") as an inventor. Exh. 173, Pet. to Correct Inventorship, Oct. 29, 1988; Exh. 16, Excerpt of File History of U.S. Patent No. 5,128,015, at B1 ("'015 Patent History").

The original application contained broad claims directed to methods and devices for measuring materials in body fluids that consisted of placing the sample fluid in an electrochemical cell containing a chemical that reacts with a substance in the sample, thereby creating an electrical current, and measuring the current when a potential is applied to the cell. '295 App. History, at A17-A20. Specifically, the original claim that eventually issued as claim 1 of the disputed patents read:

[1]For simplicity, and similarly to the parties, the Court will refer to the original owners/inventors' corporate entities, of which there were three (Life-Chek, Med-Chek, and Tall Oak Ventures), as "Tall Oak."

> 1. A method for measuring the amount of a selected compound in body fluids comprising
>
> a. placing a sample of fluid to be tested in a sample cell having first and second electrodes;
>
> b. mixing said blood with an oxidant and a buffer;
>
> c. applying a potential across said electrodes and sample; and
>
> d. measuring the resulting current to determine the concentration of said select compound present in said sample.

Id. at A17. The patent examiner rejected this broad claim, and the apparatus claims that read similarly, over certain prior art. *Id.* at A26-A34.

In the CIP application, to overcome the examiner's prior art objection, the inventors amended the pertinent claims to require that the reaction proceed "substantially to completion" and that the measured current be a "Cottrell current." *See* Exh. 16, '015 Patent History, at B5. The inventors argued that their amendments rendered the claims patentable because the prior art failed to teach or suggest measuring the "Cottrell current" after the reaction in the sample well had gone to "completion." *Id.* at B28-B30 (distinguishing Mase *et al.*). The patent examiner accepted the inventors' reasons to distinguish the prior art and allowed the claims. *Id.* at B44. The application issued as U.S. Patent No. 5,128,015 (the "'015 patent"), on July 7, 1992. Exh. 17, U.S. Patent No. 5,128,015 ("'015 Patent"). The '015 patent is a device patent.

In a divisional application, which contained the method claims that corresponded to the invention of the '015 patent, Tall Oak also amended the claims to require "substantial completion" and "Cottrell current" elements. Exh. 18, Excerpt of File History of U.S. Patent No. 5,108,564, at C7-C8 ("'564 File History"). The patent examiner used the same reasoning to allow the claims of the divisional application as he did to allow the claims of the '015 patent, because the inventors had made their arguments about patentability as to both the device and the method applications prior to

filing the divisional application. *See id.* at C10; Exh. 16, '015 File History. The divisional application issued as the '564 patent on April 28, 1992. Exh. 19, U.S. Patent No. 5,108,564 ("'564 Patent").

B. THE ABSTRACTS

Tall Oak originally hired Thomas Wettach ("Wettach"), then with Pittsburgh law firm Reed, Smith, Shaw & McClay, to draft a patent application. *See* Exh. 105, Arb. Hr. Tr. Day 2, Pottgen-Direct, at 50. Wettach's notes from April or May 1987, indicated that Dr. Pottgen told Wettach about a presentation in St. Louis, however, Wettach recalled that he thought the presentation referenced there was to occur in the future. Exh. 77, Wettach Notes, at Bates No. TW0000089; Wettach Feb. 23, 2005, Dep. at 22-23. Wettach has no record of receiving any published or written information from the presentation. Wettach Feb. 23, 2005, Dep. at 31.

Wettach continued working on the Tall Oak applications after his talk with Pottgen in April or May 1987, but based on the advice of a consultant, Dr. Jules J. Haberman ("Dr. Haberman"), in January 1988, Tall Oak retained George Yahwak ("Yahwak") to draft and prosecute the original application filed on March 15, 1988. Exh. 66, Letter, From Jules J. Haberman to Dr. Paul Pottgen, Jan. 16, 1988; Exh. 110, Arb. Hr. Tr., Pottgen, at 149-50; Exh 105, Arb. Hr. Tr. Day 2, Pottgen as Witness, at 50-51. By the time Yahwak filed the original application he had only spoken with Dr. Pottgen and Szuminsky. Yahwak July 22, 1996, Dep. at 20. However, Yahwak had reviewed Dr. Talbott's thesis by then. *Id.* at 21-22. Moreover, Yahwak had noticed that some of the figures in the draft application were identical to those in Dr. Talbott's thesis. *Id.* at 26-27. Both Dr. Pottgen and Szuminsky testified that Drs. Jordan and Talbott were responsible for the electrochemistry part

of the invention. Pottgen May 26, 2005, Dep. at 23; Pottgen May 7, 1996, Dep. at 471 (describing the "other inventors" as electrochemists); *Roche v. Bayer* Tr., Szuminsky-Direct, at 209 (describing the different duties of the inventors).

Also early in the prosecution process of the original application, Yahwak reviewed an article written by Drs. Talbott and Jordan entitled "A New Microchemical Approach to Amperometric Analysis," published in the MICROCHEMICAL JOURNAL ("MICROCHEMICAL JOURNAL article"). Exh. 20, A New Mircrochemical Approach to Amperometric Analysis, MICROCHEMICAL JOURNAL, Vol. 37, No. 1 (Academic Press, Inc. Feb. 1988) ("MICROCHEMICAL JOURNAL Article"); Yahwak Aug. 8, 2002, Dep. at 44-47. Yahwak testified that some of the language on the invention disclosure form signed by Dr. Pottgen and Szuminsky for the original application is the same language that appears in the article. Yahwak July 22, 1996, Dep. at 76.

In June 1988, Yahwak indicated to Dr. Pottgen that he thought the article should be submitted to the patent office for its review. Exh. 11, Letter, From George Yahwak to Paul Pottgen, Ph.D., June 28, 1988 ("Yahwak June 1988 Letter"). Moreover, Yahwak indicated that the article references a presentation "at the 1986 Benedetti-Pichler Award Symposium held at the Eastern Analytical Symposium, October 24, 1986." MICROCHEMICAL JOURNAL Article, at 5 n.1. *See also* Exh. 11, Yahwak June 1988 Letter, at 2. Yahwak wrote to Dr. Pottgen that "[i]t's imperative I determine whether if [sic] there was a written hand-out or abstract discussing this technology given at this talk, and if so, that I obtain a copy." Exh. 11, Letter, From George Yahwak to Paul Pottgen, PhD., June 28, 1988. Yahwak testified in a deposition that any written materials from the Symposium "would have an impact on the application," Yahwak Aug. 8, 2002, Dep. at 49, for both inventorship and prior art purposes. *Id.* at 48. Yahwak could not recall seeing an abstract, therefore, Yahwak

concluded none existed. *Id.* at 68-69. But, Yahwak recalled that the "talk was very, very broad, disclosed a lot of things about the prior art, nothing really about – nothing new." *Id.* at 67. When asked why Yahwak did not complete a patent office prior art search before filing the March 15, 1988, application, Yahwak testified that the time constraint of a March 15, 1988, press conference prevented him from doing such a search. Yahwak July 22, 1996, Dep. at 39-42; Yahwak Aug. 8, 2002, Dep. at 45. In addition, at the same time he was investigating the prior art after filing the original application, Yahwak testified that he spent lots of time trying to determine the appropriate inventors. Yahwak July 22, 1996, Dep. at 86-87.

Dr. Pottgen was aware that the abstract referenced in the MICROCHEMICAL JOURNAL article existed because Dr. Talbott had prepared a list of publications he thought were relevant to patentability that included a designation of an abstract from the Eastern Analytical Symposium ("EAS") and had provided the list to Dr. Pottgen. Talbott Apr. 22, 2002, Dep. at 82-83; *Roche Diagnostics Corp. v. Bayer Corp.*, IP00-1103-C-M/S, Trial Tr. Talbott-Direct, at 1484-85 (Feb. 6, 2003) ("*Roche v. Bayer* Tr."); Exh. 21, Publications Relevant to Med-Chek's patent, undated. In fact, Dr. Talbott's list identified two abstracts, the one referenced in the MICROCHEMICAL JOURNAL article, and the other entitled "Enzymatic Chronoamperometry," which was a synopsis of a seminar Drs. Talbott and Jordan presented at the Federation of Analytical Chemistry and Spectroscopy Society ("FACSS") meeting, in St. Louis, Missouri, September 29, 1986. Exh. 21, Publications Relevant to Med-Chek's patent, undated. Moreover, D. Michael Young ("Young"), an attorney at Roche, testified at the trial in this matter, that in 1995 he found a copy of both the EAS abstract and the FACSS abstract in Dr. Pottgen's files, which may have been given to Roche as early as late 1988. *Roche v. Apex* Tr., Young-Direct, at 133-34; Pottgen, May 6, 1996, Dep. at 115.

The evidence also shows that Dr. Talbott had informed Dr. Pottgen that he and Dr. Jordan were making a presentation at the EAS. Pottgen May 6, 1996, Dep. at 53-54. Dr. Pottgen did not attend that Symposium nor did he know whether or not Drs. Talbott and Jordan talked about a glucose sensor at the event, but he understood that Dr. Talbott talked about "very little." *Id.* at 55. Dr. Pottgen testified that he was not concerned about the content of the abstract for this talk nor the one at the St. Louis meeting "[b]ecause [he] had spoken to Dr. Jordan in the beginning . . . and emphasized to him that it was important that I have an oversight of things that are divulged either in papers or presentations . . . and that it was important that things that are proprietary be kept proprietary." *Id.* at 68-69. Moreover, Dr. Pottgen testified that Dr. Jordan's work was all laboratory experiments that had never been used by diabetics for in-home use; in other words, it did not practice the invention of the joint patent. *Id.* at 102. *See also* Exh. 105, Arb. Hr. Tr.-Pottgen, at 43 (stating that Dr. Jordan's articles, and presumably by reference the abstracts, only dealt with aqueous solutions, not blood). Although Dr. Talbott was not concerned that the abstract from the EAS talk disclosed a single point of the invention that was patentable, he was concerned about the presentation from the standpoint that it disclosed "a two-step process; first, a completion reaction and then a measurement of a current as the second step," or in other words it disclosed "the whole concept . . . ." *Roche v. Bayer* Tr. Talbott-Direct, at 1493-84.

The first abstract published, the one from the FACSS meeting stated, in relevant part:

> ENZYMATIC CHRONOAMPEROMETRY. Joseph Jordan and Jonathan Talbott, Department of Chemistry, 152 Davey Laboratory, The Pennsylvania State University, University Park, PA 16802.
>
> Combination of potentiostatic and enzymatic selectivities provides the basis for a "fail-safe" approach to clinical chemistry. The principle of "enzymatic chronoamperometry" involves the following methodological sequences

I. CHEMICAL GENERATION OF AN ELECTROREACTIVE [sic] MOIETY, "Red," with the aid of an enzyme catalyzed reaction of the type X + Ox = X' + Red, which proceeds to virtual completion in t_1 sec. [sic] and where X denotes an oxidizable metabolite.

II. ELECTROOXIDATION [sic] of the moiety "Red," yielding reconversion to "Ox," viz. [sic], Red + ne = Ox, and QUANTITATION [sic] of the concentrations

$$C_x(t=0) = C_{X'}\ (t>t_1) = C_{Red}(t>t_1)$$

via the Cottrell Current

$$i = nFA(\pi D_{Red}t)^{-0.5} \bullet C_{Red}$$

That current is measured at a judiciously selected time, $t>t_1$, and at a controlled potential where: (a) reconversion of "Red" to "Ox" is virtually complete; (b) 100% current efficiency prevails.

Capabilities of enzymatic chronoamperometry are documented by the determination of glucose in microliter samples, using miniaturized electrolysis cells and sputter-deposited thin film electrodes. Novel substituted quinone oxidants were synthesized, "tailor made" for completing rapidly the conversion of β-D-glucose to gluconic acid in the presence of the enzyme glucose oxidase.

Exh. 363, Abstract 219, FACSS 13th Annual Meeting, Sept. 28-Oct. 3, 1986, St. Louis, MO, Final Program ("FACSS Abstract"). The second abstract published, the one from the EAS in October 1986, and referenced in the MICROCHEMICAL JOURNAL article, stated, in relevant part:

A NEW MICROCHEMICAL APPROACH TO AMEROPMETRIC ANALYSIS. Joseph Jordan and Jonathan Talbott, Department of Chemistry, The Pennsylvania State University, 152 Davey Laboratory, University Part, PA 16802.

The enzyme glucose oxidase exhibits a paradoxical combination of features. On the one hand, it is extremely specific for the substrate β-D-glucose. On the other hand, it is capable of accommodating very diverse oxidizing agents. Thus, electron acceptors as different as dioxygen and fericinium salts can be effective in reactions of the type:

Glucose + Ox = Gluconic Acid + Red (1)

> Under experimental conditions where Reaction 1 proceeds to virtual completion, electrooxidation [sic] of by-product "Red" affords an attractive amperometric option for quantitation [sic]. Feasibility is documented by using "tailor-made" quinones (Q), synthesized ad-hoc, as oxidants in Reaction 1. Quantitation [sic] is accomplished in situ by determining the corresponding hydroquinone (H2Q) products via chronoamperometry at controlled potential based on the process:
>
> H2Q = Q + 2H+ + 2e- (2)
>
> Reactions 1 and 2 were implemented in miniaturized disposable cells with sample volumes in the microliter range, using as indicator electrodes novel ultrathin film microamperometric palladium sensors, which were appropriately potentiostated versus a reference electrode. These innovations may provide a breakthrough in clinical chemistry leading to novel microscale monitors of blood glucose for nonhospitalized diabetics. Similar developments are envisioned for other significant clinical analysis problems affecting the chronically ill.

Exh. 582, Abstract 338, EAS, Inc., Oct. 20-24, 1986, New York, NY, New York, NY ("EAS Abstract").

Yahwak had no copies of the abstracts in his files nor did he submit the MICROCHEMICAL JOURNAL article, the EAS abstract or the FACSS abstract to the PTO.

C. DISCOVERY OF THE MATSUSHITA REFERENCE

In December 1988, Tall Oak entered into an option agreement with Boehringer Mannheim Corporation ("BMC"), Roche's predecessor-in-interest, for a license to Tall Oak's technology described by Tall Oak's patent application. Exh. 41, Tall Oak Protest, '268 Patent History, at D95-106. As part of its due diligence under the option agreement, in September and October 1989, BMC had discovered patented technology owned by Matsushita Electric Industrial Co., Ltd. ("Matsushita"), with a publication date of December 31, 1986, WO 86/07632.[2] Exh. 25, Memo,

[2]The parties and the Court agree that Japanese publication WO 86/07632, EPO 0 230 472 ("EPO 472"), and U.S. Patent No. 4,897,173 (the "'173 patent") appear to be the same

From M. Kenemore to J. Hurrell, BMC, Sept. 21, 1989; Exh. 28, Letter, From M. Kenemore to G. Yahwak, Oct. 20, 1989.

Based on the claims of the Tall Oak application as they existed at the time, on the opinion of outside counsel, and on the basis of internal analysis, BMC concluded that the Matsushita reference anticipated the "two-step process" of Tall Oak. Exh. 25, BMC Memo, From M. Kenemore to J. Hurrell, Sept. 21, 1989; Exh. 32, BMC Memo, Subject: Life-Check, Summary Rep. of Patent Eval. Activities, From M. Kenemore to K. Pollmann, Feb. 12, 1990. BMC brought the Matsushita reference to both Dr. Pottgen's and Yahwak's attention via letters dated October 19 and 20, 1989.[3] Exh. 33, Letter, From M. Kenemore to G. Yahwak, Oct. 19, 1989; Exh. 28, Letter, From M. Kenemore to G. Yahwak, Oct. 20, 1989. In the letters, BMC gave Tall Oak the opportunity to explain how its invention was different from that disclosed in the Matsushita reference. Exh. 28, Letter, From M. Kenemore to G. Yahwak, Oct. 20, 1989. Yahwak responded via letter dated November 7, 1989, to represent that he would bring the Matsushita reference to the patent examiner's attention in a CIP application and present Tall Oak's arguments why the claimed subject matter was patentable over the reference. Exh. 35, Letter, From G. Yahwak to M. Kenemore, Nov. 7, 1989, at 2. At the time, Yahwak distinguished Matsushita in several ways: the Tall Oak invention did not utilize an immobilized enzyme; the Tall Oak invention did not require three separate electrodes or that the electrodes be made of certain materials; and the Tall Oak invention required

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technology invented by Matsushita scientists Shiro Nankai, Meriko Kawaguri, Takashi Iljima. WO 86/07632 has the earliest publication date of December 1986. The Court will call these reference generically the "Matsushita reference" or "Nankai."

[3]Evidence suggests that Szuminsky knew about the Japanese Matsushita reference as early as March 15, 1989, but felt the Tall Oak technology was "distinct from theirs." Exh. 72, Letter, From Neil J. Szuminsky to Martin Gerber, BMC, Mar. 15, 1989.

"the measurement of Cottrell current following a period during which the oxidation of glucose by glucose oxidase goes to completion." *Id.* Yahwak also expressed the necessity of amending the claims to emphasize "that the critical and essential novelty of [the Tall Oak] invention lies in measurement of the Cottrell current." *Id.* at 3. Instead of addressing BMC's concerns more specifically than he already had, Yahwak suggested a meeting between Tall Oak and BMC. *Id.*

A meeting between Tall Oak and BMC occurred on November 10, 1989. Exh. 36, BMC Memo, Subject: Life-Chek Option Agreement, From G.A. Bush to Distribution, Nov. 16, 1989. BMC's internal memos suggest that "[t]he conclusion of the group was that there is no reasonable claim in the Life-Chek application which is not in the prior art for the described technology." *Id.* However, Tall Oak asked for more time to research the issue more thoroughly because the inventors felt there were system attributes that were not already described by prior art. *Id.* In a response dated December 8, 1989, Tall Oak reiterated its opinion to BMC that the Tall Oak technology was patentable over the Matsushita reference. Exh. 83, Letter, From Paul A. Pottgen to Dr. Wolfgang Gruber, BMC, Dec. 8, 1989, at 1-2. In the letter, Tall Oak referred to the opinion of Professor Stephen Weber ("Dr. Weber"), University of Pittsburgh, who, after reviewing the Matsushita patent "concluded that there was insufficient information to determine the electrochemical basis for the current measurement." *Id.* at 2. Tall Oak also told BMC that Yahwak intended to file a preliminary amendment to disclose the Matsushita reference and distinguish it over prior art. *Id.* at 1.

BMC remained unconvinced, and by letter dated December 27, 1989, BMC notified Tall Oak that it elected not to exercise its option to a license. Exh. 37, Letter, From Dr. Wolfgang Gruber, BMC to Paul A. Pottgen, Life-Chek, Dec. 27, 1989. Despite Tall Oak's arguments to the contrary, BMC concluded that "the broad concept is not patentable because of the Matsushita publication."

Id. at 1. Moreover, the more narrow claims, including the "'auto-start concept," would not have the same value as the broader claims that cover "'end-point' technology." *Id.* at 2.

Although BMC's abandonment of the license apparently left Tall Oak without funding, *see* Exh. 2, BMC Memo, Subject Notice of Allowance Issued by Patent Examiner for U.S. Patent App. Serial No. 322,598, From P. Douglas Walling to Distribution, Jan. 2, 1992, at 1, Tall Oak continued to pursue patent protection for its technology. *Id.*; Aug. 19, 1996, Arb. Hr.Tr.-Pottgen, at 232-33.

D. DR. POTTGEN HIRES ANOTHER PATENT FIRM

At least by January 1990, Dr. Pottgen began to consider whether Tall Oak should change its patent counsel. Exh. 99, Pottgen May 6, 1996, Dep. at 371. His first step was to ask a local law firm to review objectively everything that had transpired, which was partly at the behest of a venture capital firm through which Dr. Pottgen was seeking financing. *Id.*; Exh. 105, Arb. Hr. Tr. Pottgen-Cross, at 146-47. By February 1990, Dr. Pottgen had hired attorney Rita Rooney ("Rooney"), then with law firm Eckert Seamans Cherin & Mellott, in Pittsburgh, Pennsylvania, to continue prosecuting the patent for Tall Oak's technology. Exh. 85, Letter, From Rita Rooney, Eckert Seamans Cherin & Mellot, to Paul A. Pottgen, Med-Check Labs., Inc., Feb. 12, 1990. Dr. Pottgen believed that Rooney "seemed to have a much better understanding [of the technology] and had a better way of communicating that information" than Yahwak. Exh. 99, Pottgen May 6, 1996, Dep. at 446.

After Yahwak learned that Tall Oak had retained new counsel, he provided Dr. Pottgen with a list of open items related to the patent applications. Exh. 68, Letter, From G. Yahwak to Paul A. Pottgen, Med-Chek Laboratories, Inc., Mar. 8, 1990. The list included items related to U.S. Patent

Application No. 188,864, and U.S. Patent Application No. 322,598, as well as several action items related to foreign filings. *Id.* However, there is no mention of the Matsushita reference or the abstracts. *Id.*

Rooney clearly discussed the Matsushita reference with Dr. Pottgen and Szuminsky because she memorialized the conversation in a memorandum to her file dated March 5, 1990. Exh. 73, Eckert Seamans Cherin & Mellott Memo, From R.M. Rooney to File, Mar. 5, 1990. In fact, the memorandum discusses at least ten different points of distinction between the Matsushita reference and the Tall Oak technology. *Id.* Rooney also drafted amendments to claim 1, and other claims, of the then-pending CIP application to include the reconstitution step, the allowing the reaction to proceed substantially to completion step, and the Cottrell current step. Exh. 76, Letter with Attach., From R.M. Rooney to Paul A. Pottgen, Life-Chek, June 1, 1990. As discussed above, these amendments were made, in part, to overcome a prior art objection made by the patent examiner. *See* Exh. 16, '015 Patent History, at B5.

Rooney testified that she did not recall receiving Yahwak's United States application files by the time she filed the preliminary amendment in June 1990. *Roche v. Bayer* Hr. Tr., Rooney-Direct, at 68. Moreover, Rooney testified that she never met with Drs. Jordan and Talbott. Rooney Apr. 8, 2003, Dep. at 31. Rooney had also not seen the EAS and FACSS abstracts or the MICROCHEMICAL JOURNAL article prior to her deposition in 2003. *Id.* at 32-36. Rooney testified that her only information about the invention came from Dr. Pottgen and Szuminsky, although she recalls that those inventors were articulate about the invention, particularly Szuminsky. *Id.* at 55-56.

Rooney submitted the Matsushita reference to the patent examiner via an attachment to the preliminary amendment she filed in June 1990. Exh. 86, Preliminary Amendment to U.S. Patent

App. Serial No. 322,598, June 13, 1990, at 10 (pointing the examiner to the attached Form 1449); Exh. 88, Letter, From R.M. Rooney to Paul A. Pottgen, Life-Chek, Inc., Sept. 12, 1991, at 3 (referencing that a PTO Form 1449 listing Matsushita was filed with the preliminary amendment). Furthermore, in a letter to Dr. Pottgen memorializing a meeting with Dr. Pottgen and Szuminsky, Rooney specifically identifies the reaction going to completion in Tall Oak's invention as novel over the Matsushita reference. Exh. 88, Letter, From R.M. Rooney to Paul A. Pottgen, Life-Chek, Inc., Sept. 12, 1991, at 1.

Apparently, the patent examiner did not consider the Matsushita reference because of a clerical error in the patent office. *Roche v. Apex* Tr. Young-Direct, at 85-86. Tall Oak's technology issued as the '564 patent with claim 1 remaining unchanged from the version in the preliminary amendment filed by Rooney in June 1990. *Compare* Exh. 16, '015 Patent History, at B5, *with* Exh. 19, '564 Patent, col. 14, *ll.* 25-39. Specifically, claim 1 of the '564 patent reads:

> 1. A method of measuring the amount of a selected compound in body fluids comprising,
> a) providing a measuring cell having at least a first and second electrode and said cell containing an oxidant and a buffer,
> b) placing a sample of fluid to be tested in said cell,
> c) reconstituting said oxidant and buffer with said sample fluid to generate a predetermined reaction,
> d) allowing said reaction to proceed substantially to completion,
> e) applying a potential across said electrodes and sample, and
> f) measuring the resulting Cottrell current to determine the concentration of said selected compound present in said sample.

Exh. 16, '564 Patent, col. 14, *ll.* 25-39.

The patent examiner wrote the following when he allowed the '564 patent to issue:

> The following is an Examiner's Statement of Reasons for Allowance: The prior art cited by the examiner fails to teach the key feature of the applicants invention which is providing a measuring cell having at least two electrodes wherein the cell contains an

> oxidant and a buffer and a sample fluid is introduced into the cell thereby reconstituting the oxidant and buffer with a sample fluid to generate a predetermined reaction and allowing the reaction to provide [sic] substantially to completion; and applying a potential across the electrode and sample, then measures the resulting Cottrell current to determine the concentration of selected compound present in the sample.

Exh. 18, '564 History, at C10.

In November 1991, Dr. Pottgen informed Mr. Max Kenemore ("Kenemore") of BMC of the PTO's notice of allowance of the '564 patent claims. Exh. 74, Letter, From Paul A. Pottgen, Tall Oak Ventures, to Andre de Bruin, BMC, Jan. 28, 1992, at 2. Apparently, Kenemore expressed no interest in obtaining a license, and suggested that BMC may try to invalidate the patents. *Id.* Dr. Pottgen, via letter, followed up with BMC about its lack of interest in the technology and its intent to invalidate it, in January 1992. *Id.*

Roche purchased the Tall Oak patent estate in late 1992. *Roche v. Apex* Trial Tr., Young-Direct, at 110. However, responsibility for prosecution of the patent applications in Canada, Europe and Japan remained with Tall Oak. Pottgen May 26, 2005, Dep. at 54-55. On April 2, 1996, in a response to the European Patent Office ("EPO"), regarding the MICROCHEMICAL JOURNAL article that had recently been cited to the EPO, the attorneys acting on behalf of Tall Oak, Lloyd, Wise, Tregear & Co., stated:

> we should like to make it clear that, although both authors of D6 (Microchemical Journal 37, 5-12 (1988)) are designated inventors of the above-captioned European patent application, none of the inventors were aware that this article had been published before the earliest priority date of the above-captioned application until a few days before the issue of the Communication pursuant to Article 115(2) EPC and the observations enclosed therewith . . . .

Exh. 127, Letter, From P.C. Allam, Lloyd, Wise, Tregear & Co. to EPO, Apr. 2, 1996. *See also* Exh. 128, Letter, From P.C. Allam, Lloyd, Wise, Tregear & Co. to EPO, Apr. 25, 1996 (bringing the

Matsushita reference to the attention of the EPO). The EPO rejected the application over the inventor's arguments that the claims were patentable despite the MICROCHEMICAL JOURNAL article because the article disclosed the "inventive step" of the new technology. Exh. 129, EPO Consultation by Telephone, RE: App. No. 89907316.0, May 9, 1996.

In September 1996, the inventor's Canadian patent counsel submitted the EAS abstract to the Canadian Patent Office ("CANPO"). Exh. 569, Resp. to Office Action, Patent App. S.N. 601,657, Sept. 23, 1996. The Canadian version of the patent issued on Apr. 27, 1999. Exh. 543, Canadian Patent No. 1,340,516 (Apr. 27, 1999); Szuminsky, May 26, 2005, Dep. at 87.

II. STANDARD

The defense of inequitable conduct arises from a patent applicant's[4] breach of the duties of candor, good faith and honesty in prosecuting an invention. *See Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995). Success with such a defense renders the patent unenforceable. *Purdue Pharma L.P. v. Boehringer Ingelheim GMBH*, 237 F.3d 1359, 1366 (Fed. Cir. 2001). To prove their defense, Defendants must establish by clear and convincing evidence "misrepresentation or omission of a material fact, together with an intent to deceive the PTO." *Hoffmann-LaRoche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1359 (Fed. Cir. 2003). Once Defendants have evidenced the requisite levels of materiality and intent, the Court, considering all the circumstances, "must

[4]"Applicant" in this context "includes anyone under a duty to disclose material information to the PTO pursuant to 37 C.F.R. § 1.56, namely: the inventor, the prosecuting attorney or agent, and anyone associated with the inventor or the assignee who is substantially involved in the preparation or prosecution of the application." *Bruno Ind. Living Aids, Inc. v. Acorn Mobility Servs., Ltd.*, 394 F.3d 1348, 1351 n.3 (Fed. Cir. 2005) (citing *Molines PLC*, 48 F.3d at 1178 n.6).

determine whether the equities warrant a conclusion that the patentee has engaged in inequitable conduct." *Id.* (citing *Molins PLC*, 48 F.3d at 1178). *See also Purdue Pharma*, 237 F.3d at1366 (stating that once the threshold findings are made, the Court must weigh "the materiality and intent in light of all the circumstances to determine whether the applicant's conduct is so culpable that the patent should be held unenforceable").

With respect to the element of materiality, two standards apply in this case, one to the prosecution of the '564 patent, and one to prosecution of the reissue patent, the '268 patent. The '564 patent was prosecuted prior to 1992. For patents prosecuted prior to 1992, information is material "when there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue." *Hoffmann-LaRoche, Inc. v. Crystal Chem. Co.*, 323 F.3d 1354, 1367 (Fed. Cir. 2003). For patents prosecuted after March 16, 1992, information is material when:

> [I]t is not cumulative to information already of record or being made of record in the application, and
>
> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
>
> (2) It refutes, or is inconsistent with, a position the applicant has taken in:
>
> (i) Opposing an argument of unpatentability relied on by the Office, or
>
> (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(b) (2004). *See also Bruno*, 394 F.3d at 1352-53 (applying new PTO rule to materiality determination).

The second threshold requirement is intent to deceive. Intent is rarely proven by direct evidence; it "is generally inferred from the facts and circumstances surrounding a knowing failure

to disclose material information." *Id.* at 1354 (citing *Paragon Podiatry Lab., Inc. v. KLM Labs. Inc.*, 984 F.2d 1182, 1193 (Fed. Cir. 1993)). However, gross negligence alone is insufficient to establish intent. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 876 (Fed. Cir. 1988). The *Kingsdown* court stated that "the involved conduct, viewed in light of all the evidence, including evidence of good faith, must indicate sufficient culpability to require a finding of intent to deceive." *Id.*

III. DISCUSSION

Defendants have charged Dr. Pottgen with inequitable conduct because he intentionally withheld the abstracts from the PTO during the initial prosecution of the '564 patent. The Court finds that Defendants have met their burden to show by clear and convincing evidence that inequitable conduct occurred.

A. MATERIALITY OF THE ABSTRACTS

In the initial prosecution,[5] the Court finds that there is clear and convincing evidence that the abstracts were material. As stated above, in 1988 a reference was material if "there [was] a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue." *Hoffmann-LaRoche, Inc. v. Crystal Chem. Co.*, 323 F.3d 1354, 1367 (Fed. Cir. 2003). At the outset, based on the testimony of Drs. Turner and Weber at trial, the Court finds that at the time of the invention the prior art was crowded and electrochemical methods

[5]The Court does not intend for this discussion of the materiality of the abstracts to reflect how the analysis of materiality would come out with respect to the reissue process.

for the measurement of glucose had been patented. In addition, the level of knowledge of one of ordinary skill in the art at the time of the invention was relatively high because of the plethora of development in the biosensor area.

Both abstracts were published in October 1986, well before a year prior to the March 15, 1988, filing date of the original application. There is no real challenge to the fact that the abstracts were published; therefore, the abstracts could be considered prior art publications if they teach or disclose any aspect of the invention. The Court finds that several key aspects of the patented invention were disclosed by the abstracts.

While the EAS abstract is more general than the FACSS abstract about the reaction sequence, both abstracts disclose a two-step analytical process for measuring the concentration of either a "metabolyte," in the case of the FACSS abstract, or "β-D-glucose," in the case of the EAS abstract, using an electrochemical technique. This two-step process, which Dr. Pottgen testified was a term coined by Dr. Jordan, *see* Pottgen May 7, 1996, Dep. at 446, was part of the claimed invention, even in the earliest form of the claims.

In addition to the two-step process, both of the abstracts disclose that the first reaction, the oxidation reaction, proceeds to "virtual completion." The difference between this requirement and the requirement of "substantially to completion" that ended up in the claims that issued in the '564 patent is insignificant. The Court finds that the abstracts clearly illuminated this requirement of claim 1.

Moreover, the FACSS abstract teaches that the second step, the one in which the concentration of an analyte is measured, requires the use of "Cottrell current," for which the practitioner is directed to use the Cottrell equation. That the abstract has an error in the equation as printed is immaterial

in light of Dr. Turner's testimony and Roche's expert's, Dr. Weber, testimony that one of ordinary skill in the art would know because of the reference to "Cottrell" that the intended equation was the one elucidated by Frederick Gardner Cottrell. This part of the FACSS abstract teaches the other element upon which Rooney distinguished the prior art. The Court found credible Dr. Weber's testimony at trial that the term "Cottrell current" did not appear in the published literature prior to the inventor's use of the term in their patent prosecution. However, its appearance in the abstract, coupled with the printed Cottrell equation, would have alerted one of ordinary skill in the art that "Cottrell current" used to perform the experiments described in the abstract would be one that followed the Cottrell equation. In other words, the FACSS abstract discloses the use of "Cottrell current" to determine the amount of "glucose in microliter samples [and] miniaturized electrolysis cells . . . ." Exh. 363, FACSS Abstract. This is clearly within the subject matter of the '564 patented invention.

Further, the EAS abstract specifically identifies that the technology may have application in the "nonhospitalized diabetic" blood glucose monitoring market. Exh. 582, EAS Abstract. The specification of the '564 patent clearly identifies the invention as one focused on this kind of market. Moreover, the blood glucose monitoring market, as Defendants' expert, Dr. Peter Francis Turner ("Dr. Turner"), testified to at trial, was burgeoning with new technology at the time of the invention, particularly new electrochemical techniques. The two abstracts, considered together, are particularly close to describing the method claimed in claim1 of the '564 patent.

Roche contends that the abstracts were not material because they are not "enabling."[6]

[6]As a supplement to its non-enabling argument Roche spent much time during the trial distinguishing the abstracts from the claimed invention on the basis of the non-disclosure of "tailor-made quinones." However, the "tailor-made quinones" are not part of the invention

Moreover, Roche presented the testimony of three inventors, Drs. Pottgen and Talbott, and Szuminsky, as well as that of Dr. Weber, that the abstracts did not teach the "know how and show how" of the patented method. Pottgen May 6, 1996, Dep. at 75. *See also* Talbott, Apr. 22, 2002, Dep. at 75 (stating that the presentations did not encompass all of the patented invention); Szuminsky, May 26, 2005, Dep. at 50-51 (discussing the EAS abstract) Exh. 89, Weber Report, Mar. 18, 2005, at 6-21. The Court construes this testimony to mean that the abstracts were not enabling. But the enablement inquiry is only pertinent if the reference teaches nothing at all. The Federal Circuit has held that under 35 U.S.C. § 103, or the obviousness statute, "a reference need not be enabled; it qualifies as prior art, regardless, for whatever is disclosed therein." *Amgen Inc. v. Hoechst Marion Roussell, Inc.*, 314 F.3d 1313, 1357 (Fed. Cir. 2003) (citing *Symbol Techs., Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1578 (Fed. Cir. 1991) *Reading & Bates Constr. Co. v. Baker Energy*, 748 F.2d 645, 652 (Fed. Cir. 1984)). *See also Beckman Instrs., Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989) (stating that "[e]ven if a reference discloses an inoperative device, it is prior art for all that it teaches"). As discussed above, the abstracts did teach a two-step process, wherein in the first step, an oxidation reaction would proceed substantially to completion and in the second step, a potential is applied, the current is measured, and the concentration of an analyte is determined using the Cottrell equation. These elements were not in the other prior art before the examiner during the original prosecution, and were the elements Rooney relied upon to distinguish the invention from the prior art cited by the examiner. Moreover, the Court found reasonable Dr. Turner's testimony that experiments in the abstracts could be reproduced by one of ordinary skill in

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claimed in the '564 patent. As a result, the Court was not persuaded by testimony that the missing "tailor-made quinone" detail rendered the abstracts either non-enabling or immaterial.

the art at the time of invention, particularly from the FACSS abstract. This is enablement enough to find the abstracts material.

Furthermore, in arguing for the patentability of the amended claims that recited the "substantially to completion" and "Cottrell current" limitations, Rooney represented that the use of "Cottrell current" for an assay was new. *See* Exh. 16, '564 Patent History, at B23, B25-26. In light of the fact that the FACSS abstract did disclose the use of "Cottrell current" to quantify a metabolyte, Rooney's statements to the examiner were misleading at the very least, if not contradictory. This makes the FACSS abstract material in an additional aspect.

In summary, although the Court disagrees with Dr. Turner that each of the abstracts alone would have enabled one of ordinary skill in the art to practice the method claimed by the '564 patent,[7] the Court finds that a reasonable examiner would have found the abstracts relevant in determining whether the '564 patent method was obvious based on these references in combination with other known prior art at the time of the initial prosecution, including the Matshushita reference. For this reason, Defendants have met their burden to show by clear and convincing evidence that the abstracts were material.

B. INTENT TO DECEIVE

The second threshold element that Defendants must prove by clear and convincing evidence, is that Dr. Pottgen intended to deceive the patent office by withholding the abstracts. The Court

[7]Dr. Turner was clearly one of extraordinary skill in the art of biosensors by 1986. As such, what the abstracts taught him is not what they would have taught someone of ordinary skill. Because he testified to what the abstracts taught him, the Court was not persuaded that one of ordinary skill would have made all of the scientific assumptions that Dr. Turner made when he opined that both abstracts anticipated claim 1 of the '564 patented invention.

finds that Defendants have met their burden to prove that Dr. Pottgen knew about the materiality of the abstracts and intentionally withheld them from the patent examiner.

Dr. Pottgen knew about both abstracts. Dr. Pottgen had a conversation with his first patent attorney, Wettach, in April or May of 1987, during which Wettach recorded that something had occurred in St. Louis, "Last 6 mos/-Oct. time," in connection with the invention. Exh. 77, Wettach Notes, at Bates No. TW0000089. Dr. Pottgen testified that he knew that Dr. Jordan had planned to make presentations in October at two seminars. Pottgen May 6, 1996, Dep. at 66-67. Dr. Pottgen also testified that he had seen the abstracts around the time of Dr. Jordan's presentations at the meetings. Pottgen May 26, 2005, Dep. at 34. In addition, Dr. Talbott testified that he had written a list of publications relevant to the Tall Oak patents while he was employed by Dr. Pottgen and that he had given the list to Dr. Pottgen. Talbott Apr. 22, 2002, Dep. at 82-83. Two of the relevant publications on that list were the abstracts. Exh. 21, Publications Relevant to Med-Chek's patent, undated. Furthermore, Young testified at trial that in 1995 he discovered the abstracts in files provided to Roche by Dr. Pottgen. *Roche v. Apex* Tr., Young-Direct, at 133-34.

There is also clear and convincing evidence that Dr. Pottgen either knew or should have known that the abstracts were material. Yahwak specifically told Dr. Pottgen in a letter dated June 28, 1988, that any abstract from Dr. Jordan's presentation at the EAS could have an impact on the application. Exh. 11, Letter, From George Yahwak to Paul Pottgen, Ph.D., June 28, 1988. The Court is convinced that if the EAS abstract could have an impact on the application, the FACSS abstract, which clearly discloses a two-step process and measurement of concentration "via Cottrell current," could also have an impact on the application. In other words, the Court finds that Dr. Pottgen could not have known about the importance of finding the EAS abstract without recognizing the

importance of finding the FACSS abstract as well. Dr. Pottgen testified the he relied upon Dr. Jordan to disclose the abstracts to Yahwak and because neither Dr. Haberman nor Yahwak continued to ask for the abstracts, Dr. Pottgen assumed Yahwak had seen them. Pottgen May 26, 2005, Dep. at 113-14, 130, 139. But, at that the time Yahwak asked for any written information from the EAS, neither Dr. Jordan nor Dr. Talbott were named inventors. Therefore, it was Dr. Pottgen and Szuminsky who were under a duty to disclose relevant references, and Dr. Pottgen knew about the abstracts well before the application was filed. *Id.* at 35. Dr. Pottgen merely had to send Yahwak copies of Dr. Jordan's correspondence, which Dr. Pottgen testified that he had received, to comply with his obligation.

There is other evidence that Dr. Pottgen knew of the materiality of the abstracts. Dr. Talbott had informed Dr. Pottgen that he was concerned about the disclosures of the technology in the MICROCHEMICAL JOURNAL article and at the seminar presentation upon which the article was based.[8] Pottgen May 6, 1996, Dep. at 53-54. Dr. Pottgen claims that he did not put much stock in Dr. Talbott's opinion, however, believing it merely evidence of the "unusual relationship" between Dr.

[8]Roche argues that Dr. Pottgen had no intent to deceive the PTO because he thought that the MICROCHEMICAL JOURNAL article was irrelevant, and because the abstracts were less enabling that the article, the abstracts were also irrelevant. *See* Pottgen May 6, 1996, Dep. at 75 (stating that the MICROCHEMICAL JOURNAL article did not disclose the "know how and show how" of the claimed invention). The Court is not persuaded by this argument. Yahwak indicated in his June 28, 1988, letter that in his opinion the MICROCHEMICAL JOURNAL article was relevant, and Dr. Pottgen testified that he was relying upon his attorneys to tell him what was relevant. Exh. 11, Yahwak June 1988 Letter; Pottgen, May 26, 2005, Dep. at 19, 27, 113-14. If Dr. Pottgen disagreed with Yahwak about the importance of the article, and by reference, the abstracts, then he misrepresented the degree to which he relied upon Yahwak's patent prosecution expertise. Moreover, the invention disclosure signed by Dr. Pottgen contained some of the same text as that found in the MICROCHEMICAL JOURNAL article and Dr. Pottgen testified that the patent was the "proprietary" part of the invention. Yahwak July 22, 1996, Dep. at 76; Pottgen May 6, 1996, Dep. at 77. Dr. Pottgen cannot have it both ways: the information common to the article and the patent cannot be both proprietary and irrelevant at the same time.

Jordan and Dr. Talbott. *Id.* at 66-67, 129-30. Yet, Dr. Pottgen identified that Drs. Jordan and Talbott were the experts in electrochemistry. Pottgen May 26, 2005, Dep. at 23. The Court does not find Dr. Pottgen's testimony credible that he would completely disregard Dr. Talbott's opinion on the importance of material that discussed the technology of the invention with respect to electrochemistry.

Furthermore, despite professing at one time that he knew nothing about the electrochemical aspects of the invention, Dr. Pottgen represented to Rooney, with Szuminsky, that one of the differences between their invention and the Matsushita reference was the measurement of "Cottrell current." Exh. 73, Eckert Seamans Cherin & Mellott Memorandum, From R.M. Rooney, To File, Mar. 5,1990, at 3, ¶ 10 (memorializing the meeting between Counsel and Dr. Pottgen and Szuminsky to distinguish the Tall Oak invention from Matsushita). Rooney testified that she learned about the Tall Oak technology from Dr. Pottgen and Szuminsky exclusively; she never met either Dr. Jordan or Dr. Talbott. *Roche v. Bayer* Inequitable Conduct Hr. Tr., May 1, 2003, at 55-57; Rooney Apr. 8, 2003, Dep. at 36. Moreover, she had not received Yahwak's United States application files prior to filing the preliminary amendment in June 1990. *Roche v. Bayer* Inequitable Conduct Hr. Tr., May 1, 2003, at 68. Therefore, she was relying exclusively on Dr. Pottgen and Szuminsky to explain the differences between the Tall Oak invention and prior art. It was during her conversations with Dr. Pottgen and Szuminsky that Rooney learned the term "Cottrell current," which, as has already been stated, was not in the chronoamperometry literature prior to its appearance in the FACSS abstract and, subsequently, in the Tall Oak patent. Clearly by the time Dr. Pottgen met with Rooney to distinguish the Matsushita reference, he knew the importance of "Cottrell current" to the Tall Oak invention, and knew where the term had been disclosed in a prior

publication. But, Dr. Pottgen never mentioned the abstract to Rooney; Rooney never saw either of the abstracts or the MICROCHEMICAL JOURNAL article (which would have prompted her to inquire about the abstracts) until 2003 during her deposition in the *Roche v. Bayer* case. Rooney Apr. 8, 2003, Dep. at 31-32.

The circumstances surrounding the manner in which Dr. Pottgen hired attorneys to prosecute the patents and gave the attorneys, or withheld from them, pertinent information about the invention leads the Court to conclude not only that Dr. Pottgen knew the abstracts were material, but that Dr. Pottgen intentionally withheld the abstracts from the PTO. Dr. Pottgen testified that he had copies of the abstracts near the time that Dr. Jordan made the presentations in October of 1986. Pottgen May 26, 2005, Dep. at 34. But, when he apparently spoke with Wettach about the talks in April or May 1987, Dr. Pottgen did not reveal the existence of the abstracts to Wettach. Wettach had no record of receiving the abstracts and testified that he had never seen them. Wettach Feb. 23, 2005, Dep. at 17-18. Wettach also testified that he would have asked Dr. Pottgen for any paper or publication related to the subject matter of the invention because that was his practice. *Id.* at 55-57.

Dr. Pottgen's conduct with Yahwak is equally questionable. First, Dr. Pottgen and Szuminsky were the only two inventors on the original patent application filed by Yahwak. Exh. 15, '295 App. History, at A1. But, Dr. Pottgen had specifically obtained the services of Dr. Jordan and his laboratory at Pennsylvania State University ("Penn State") because Dr. Pottgen did not have the ability to develop the technology himself. Pottgen May 26, 2005, Dep. at 23-25 (describing the contributions of the four inventors). In fact, both Dr. Pottgen and Szuminsky testified that the electrochemistry portion of the work was performed by Drs. Jordan and Talbott; Tall Oak was responsible for the cell construction and/or manufacturing techniques. Pottgen May 26, 2005, Dep.

at 23; *Roche v. Bayer* Tr., Jan. 29, 2003, Szuminsky, at 209. It was left to Yahwak to investigate and discover whether the work he saw in Dr. Talbott's thesis, and reflected in the MICROCHEMICAL JOURNAL article, warranted adding either or both Dr. Talbott and Dr. Jordan to the application. Exh. 11, Yahwak June 1988 Letter; Yahwak July 22, 1996, Dep. at 86-87. These facts alone lead the Court to conclude that Dr. Pottgen was acting in bad faith with respect to the prosecution of the '564 patent, however, Dr. Pottgen's failure to be candid with his attorneys did not stop there.

Yahwak's letter dated June 28, 1988, clearly outlined to Dr. Pottgen the importance of any written materials, including abstracts, that discussed the subject matter of the invention. Yahwak admitted that he had not done a thorough prior art search prior to filing the patent application because of a pending press conference. Yahwak July 22, 1996, Dep. at 39-42; Yahwak Aug. 8, 2002, Dep. at 45. It is clear that Yahwak was depending upon Dr. Pottgen, the admitted point-man with respect to business and patent issues, Pottgen Aug. 1, 2002, Dep. at 107; Pottgen May 26, 2005, Dep. at 43, to help him with the prior art search after the fact. Rather than giving Yahwak everything he had related to the work at Penn State by Drs. Jordan and Talbott, Dr. Pottgen referred Yahwak directly to Dr. Jordan. *Id.* at 113-14. This fact is particularly troubling given that Dr. Pottgen had collected the same information, or so he asserted, for BMC, just several months later. *See id.* at 43-44. Moreover, Dr. Pottgen knew that Dr. Talbott had warned Dr. Jordan that Dr. Jordan's talks might jeopardize the patentability of the Tall Oak technology, but Dr. Jordan ignored Dr. Talbott's warnings and pressed ahead. Pottgen May 6, 1996, Dep. at 67. The logical conclusion from this chain of events is that Dr. Pottgen knew the abstracts would affect the patentability of the invention and he was counting on Dr. Jordan to brush off Yahwak's inquiries about them rather than Dr. Pottgen giving Yahwak all of the information Dr. Pottgen had in his files about the Penn State

research.

Furthermore, when Dr. Pottgen changed attorneys and hired Rooney, he continued to exhibit bad faith in prosecuting the patent. Dr. Pottgen testified on several occasions that he could not speak about the invention in technical terms because he was not an electrochemist. Pottgen May 6, 1996, Dep. at 113-14; Pottgen May 7, 1996, Dep. at 470-71; Pottgen May 26, 2005, Dep. at 24-25. However, when he hired Rooney, he never introduced to Rooney the electrochemists who worked on that aspect of the invention.[9] Rooney Apr. 8, 2003, Dep. at 31. Instead, he and Szuminsky distinguished the Tall Oak invention from the Matsushita reference, including the electrochemical differences, themselves. *Id.* at 55-56. Dr. Pottgen's disclosures to Rooney included the assertion made by Dr. Weber that Matsushita did not teach "Cottrell current." Exh. 73, Eckert Seamans Cherin & Mellott Memo, Frm R.M. Rooney to File, Mar. 5, 1990. As discussed above, "Cottrell current," although apparently a familiar term to Dr. Talbott, Talbott May 25, 1996, Dep. at 143, and perhaps the other inventors, was not a term used in the chronoamperometry literature prior to Tall Oak's use of the term in connection with their invention. *Roche v. Apex* Tr. Weber-Cross. But, Dr. Pottgen, and Szuminsky, allowed Rooney to argue that the use of "Cottrell current" in the invention was new. Exh. 16, '015 Patent History, at B28-29. But the term was not "new" as that term is generally used to distinguish prior art; Dr. Pottgen knew, "Cottrell current" had been used by Dr. Jordan in the FACSS abstract to describe how to use current measurements to quantify the concentration of an analyte in 1986.

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[9]The Court notes that it is aware that Dr. Jordan died prior to the *Roche v. Bayer* litigation, however, no information to determine if Dr. Jordan was alive during prosecution of the patent in its entirety. In any event, it is clear that Dr. Talbott is still alive and would, presumably, been available to consult with Rooney.

Similarly to Dr. Pottgen's failure to disclose the abstracts in the United States, the MICROCHEMICAL JOURNAL article and the EAS abstract did not surface in the prosecution process in Canada and Europe until 1996. Tall Oak's attorneys in the Canadian prosecution determined that the EAS abstract, apparently the only one they knew about, needed submitted. Exh 569, Resp. to Office Action, Patent App. S.N. 601,657, Sept. 23, 1996. Moreover, like Rooney, it appears that the Canadian counsel was focused on the absence of "Cottrell current" to distinguish the EAS abstract, a term clearly present in the FACSS abstract, from the claims of the Tall Oak invention. Exh. 191, Facsimile, From Charles E. Kosinski, Thorp Reed & Armstrong, to Neil J. Szuminsky, Sept. 16, 1996 ("Is the claiming of Cottrell current the most significant and patentable difference?"). In Europe, in April 1996, Dr. Pottgen allowed Tall Oak's attorneys to assert to the EPO that the publication date of the MICROCHEMICAL JOURNAL article had recently been discovered by the inventors. Exh. 127, Letter, Re: European Pat. App. No. 89904316.0 TALL OAK VENTURES, From P.C. Allam, Lloyd, Wise, Tregeart Co., to EPO, Apr. 2, 1996. When questioned about this point in his most recent deposition, Dr. Pottgen denied knowledge of his attorney's understanding on the issue. Pottgen May 26, 2005, Dep. at 90-92. His denial in this regard is inexcusable because Dr. Pottgen had been communicating with his attorneys to distinguish the MICROCHEMICAL JOURNAL article's disclosures from the invention in the European application since at least February of the same year. Exh. 199, Facsimile, From P. Pottgen to M. Kline, Thorp Reed & Armstrong, Feb. 8, 1996.

The Court does not find Dr. Pottgen's testimony on his good faith credible in light of his continued failure to produce to his attorneys all the information given to him by Penn State. As the point-man for the patenting of the Tall Oak technology, Dr. Pottgen was less than candid with his

attorneys about the prior art.

For the foregoing reasons the Court finds that Defendants have proven by clear and convincing evidence that Dr. Pottgen intended to deceive the patent office when he withheld the abstracts.

C. WEIGHING THE EQUITIES

Having found the requisite evidence of materiality and intent, the Court must determine "whether under all the circumstances, the incident[] of inequitable conduct . . . justif[ies] the sanction of rendering the ['564 patent, and its progeny,] unenforceable." *Hoffman-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1372 (Fed. Cir. 2003). The Court has made findings that the abstracts were material; the FACSS abstract more material in light of its disclose of the term "Cottrell current" in conjunction with the two-step analytical method In addition, the Court has found that Dr. Pottgen withheld the abstracts from his patent attorneys with the intent to deceive the patent office. Dr. Pottgen testified that he had no economic incentive to withhold any material from the PTO. Pottgen May 26, 2005, Dep. at 130-31. However, the evidence suggests that Dr. Pottgen knew that a patent was the only way that he could profit from the invention because his small company would not be able to manufacture a product itself. In other words, in order for the technology to have value to a commercial partner like BMC or Roche, Dr. Pottgen had to patent the invention, otherwise he could not profit from it. *See id.* at 143 (describing the importance of obtaining a patent on the technology with respect to negotiations with BMC). This is evidenced by the history of Dr. Pottgen's relationship with BMC and with his business advisor, Dr. Haberman. Dr. Pottgen testified that he hired Dr. Haberman to help Tall Oak find a partner to commercialize the invention, among other things. Pottgen May 26, 2005, Dep. at 127-28. Moreover, when BMC notified Tall Oak that it

declined to exercise the option to license Tall Oak's technology, Dr. Pottgen testified that he was scrambling for ways to keep the technology, and his company, alive. *See, e.g.*, Aug. 12, 1996 Arb. Tr. Pottgen, at 146-47, 234 (testifying that he took financial responsibility for prosecuting the foreign patents); Aug. 19, 1996, Arb. Tr. Pottgen, at 232-33. At that point Dr. Pottgen knew he had to get the patent, or his hope of commercializing the technology through BMC would expire. Pottgen May 7, 1996, Dep. at 446-48.

Furthermore, the Court found Dr. Pottgen's testimony, both during the *Roche v. Bayer* proceeding and the instant proceeding, less than credible. Dr. Pottgen's testimony about his understanding of the invention is indicative of why the Court came to this conclusion. On the one hand, Dr. Pottgen testified that he could not speak to the electrochemical aspects of the invention. *See, e.g.*, Pottgen May 6, 1996, Dep. at 113-14 (discussing the disclosures in the MICROCHEMICAL JOURNAL article); Pottgen May 7, 1996, Dep. at 473-74 (distinguishing the Matsushita reference). On the other hand, Dr. Pottgen testified that the abstracts and the MICROCHEMICAL JOURNAL article did not disclose the invention because they did not disclose the "know how and show how" of the invention. Pottgen May 6, 1996, Dep. at 75. In addition, Dr. Pottgen's testimony regarding his understanding of the invention rings hollow when juxtaposed against the fact that neither Dr. Jordan nor Dr. Talbott were listed on the original patent application, despite Wettach having worked with Dr. Pottgen on the application since early 1987, and when juxtaposed against the fact that Rooney made all of her assessments about how to distinguish the Tall Oak invention from the Matsushita reference, which arguably disclosed all elements of claim 1 save "Cottrell current," based on a conversation with Dr. Pottgen and Szuminsky. *See, e.g.*, Exh. 15, '295 App. History at A1; Pottgen May 26, 2005, Dep. at 24; Exh. 77, Wettach Notes, at Bates No. TW0000089; Wettach Feb. 23,

2005, Dep. at 22-23, Exh. 73, Eckert Seamans Cherin & Mellot Memo, From R.M. Rooney to File, Mar. 5, 1990; *Roche v. Bayer* Tr.-Rooney, at 55057; Rooney Apr. 8, 2003, Dep. at 36.

In addition, Dr. Pottgen testified that he was relying upon his attorneys to tell him what was relevant. Pottgen May 26, 2005 Dep. at 19-20. If that was the case, then it seems logical that when asked by Yahwak in June of 1988 about information related to inventorship and the content of the MICROCHEMICAL JOURNAL article, that Dr. Pottgen would simply turn over copies of his files from the Penn State work to Yahwak, in addition to encouraging Yahwak to talk with Drs. Jordan and Talbott himself. This conduct is particularly troubling in light of the fact that some of the MICROCHEMICAL JOURNAL article ended up in the invention disclosure signed by Dr. Pottgen and Szuminsky in the first application. Yahwak July 22, 1996, Dep. at 76.

Unfortunately, the Court cannot ignore these inconsistencies because, as Roche argues, "the abstracts were 'just abstracts.'" The term used by the inventors to describe the measurement mechanism of the second reaction of their two-step method, "Cottrell current," which was not commonly used in the relevant literature, appeared in a context in which it could be construed to teach a novel approach to diagnostic testing at a time where such approaches were in rapid development. This aspect of the invention was the element the inventors relied upon to distinguish the closest prior art, the Matsushita reference. It is clear that a reasonable examiner would have found the FACSS abstract, at the very least, important in deciding patentability. Yet, Dr. Pottgen never turned over his files to any of his attorneys.

The Court finds that the equities weigh in favor of finding that the incident of inequitable conduct on Dr. Pottgen's part warrants the sanction of unenforceability of the '564 patent and its progeny.

IV. JUDGMENT

For the foregoing reasons the Court finds that Defendants, Apex Biotechnology Corp., Hypoguard USA, Inc., Medline Industries, Inc., and Home Diagnostics Corporation, Inc., have met their burden to prove by clear and convincing evidence that the inequitable conduct on the part of Dr. Paul Pottgen in the prosecution of U.S. Patent No. 5,108,564 should render that patent, and its progeny, in particular U.S. Patent No. Re 36,268, unenforceable.

IT IS SO ORDERED this 20th day of June, 2005.

LARRY J. McKINNEY, CHIEF JUDGE
United States District Court
Southern District of Indiana

Distribution attached.

Electronically distributed to:

Jackie M. Bennett Jr.
SOMMER BARNARD ATTORNEYS, PC
jbennett@sommerbarnard.com

Don O. Burley
FINNEGAN HENDERSON FARABOW GARRETT & DUNNER
don.burley@finnegan.com

Robert William Busby Jr.
BAKER & MCKENZIE LLP
bob.busby@bakernet.com

Helen K. Geib
BARNES & THORNBURG
helen.geib@btlaw.com

Brent Allen Harris
ROCHE DIAGNOSTICS CORPORATION
brent.harris@roche.com

David J. Hensel
SOMMER BARNARD ATTORNEYS, PC
dhensel@sommerbarnard.com

Tina E. Hulse
FINNEGAN HENDERSON FARABOW GARRETT & DUNNER L.L.P.
tina.hulse@finnegan.com

Paul B. Hunt
BARNES & THORNBURG
paul.hunt@btlaw.com

Erik Christopher Johnson
MCTURNAN & TURNER
ejohnson@mtlitig.com

Donald E. Knebel
BARNES & THORNBURG
donald.knebel@btlaw.com

Shannon D. Landreth
MCTURNAN & TURNER
slandreth@mtlitig.com

Robert D. Litowitz
FINNEGAN HENDERSON FARABOW GARRETT & DUNNER LLP
rob.litowitz@finnegan.com

Larry A. Mackey
BARNES & THORNBURG
larry.mackey@btlaw.com

William Jackson Matney Jr.
BAKER & MCKENZIE LLP
jack.matney@bakernet.com

Barbara Clarke McCurdy
FINNEGAN HENDERSON FARABOW GARRETT & DUNNER, LLP
barbara.mccurdy@finnegan.com

Lee B. McTurnan
MCTURNAN & TURNER
lmcturnan@mtlitig.com

Kristin L. Menon
FINNEGAN HENDERSON FARABOW GARRETT & DUNNER, LLP
kristin.menon@finnegan.com

Kendall H. Millard
BARNES & THORNBURG
kmillard@btlaw.com

F. Anthony Paganelli
SOMMER BARNARD ATTORNEYS, PC
paganelli@sommerbarnard.com

Erik R. Puknys
FINNEGAN HENDERSON FARABOW GARRETT & DUNNER, LLP
erik.puknys@finnegan.com

Aaron Mark Raphael
FINNEGAN HENDERSON FARABOW GARRETT & DUNNER, LLP
aaron.raphael@finnegan.com

Lynn C. Tyler
BARNES & THORNBURG
lynn.tyler@btlaw.com

Todd G. Vare
BARNES & THORNBURG
todd.vare@btlaw.com